

**REMARKS**

A Petition for Extension of Time is being concurrently filed with this Amendment. Thus, this Amendment is being timely filed.

Applicant respectfully requests the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

**Status of the Claims**

Claims 1, 2, 4-6, and 8-15 are currently pending in the present application. The Office Action is final. Claims 1, 2, 4-6, and 8-11 stand rejected. Claims 1, 5 and 11 have been amended without prejudice or disclaimer. Claims 3 and 7 were previously cancelled without prejudice or disclaimer. Claims 12-15 are new. No new matter has been added by way of amendment, because each amendment is supported by the present specification. Claim 12 has support found in the description on page 4, fourth paragraph, page 7, sixth paragraph, and page 8, third paragraph, of the present specification. Claim 13 has support found in the description on page 1, first paragraph, page 4, fourth paragraph; page 6, fourth paragraph; and page 7, first and fifth paragraphs of the present specification. Claim 14 has support found on page 8, third paragraph, of the present specification. Claim 15 has support found in the description on page 1, first paragraph page 4, fourth paragraph; page 6, fourth paragraph; and page 7, first and fifth paragraphs, and page 8, third paragraph, of the present specification.

***Examiner Telephone Interview***

Applicants' representatives thank the Examiner for extending the courtesy of the telephone interview conducted on November 29, 2007. Applicant's representatives discussed the above claim amendments with the Examiner in an effort to resolve the outstanding issues within the Office Action dated July 2, 2007. Prior to the interview, Applicants' representatives provided an amended claim set, as well as definitions and articles from the inventor, in an effort to further distinguish the claims and overcome the present rejections (please see Exhibit 1- The Preterm Parturition Syndrome, and Exhibit 2- The Length of Uncomplicated Human Gestation, enclosed herein). The Examiner stated that the claim 1 amendments overcame the prior art rejections. Applicants' representatives then inquired whether the claims would be entered and allowed. The Examiner was reluctant to either enter or allow the claims since the amendments may have new issues and a new search may be required. The Examiner also indicated that the Examiner had not had time to locate support for the new claims during an initial review. Applicants' representatives indicated to the Examiner that Applicants will point out support within the specification for the new claims within the Applicants' next response. Support has been pointed out in the preceding section above.

***Rejection Under 35 U.S.C § 112, Second Paragraph, Indefiniteness***

Claims 1, 2, 4-6 and 8-11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regards as the invention. Applicant respectfully traverses.

Applicants respectfully request reconsideration and subsequent withdrawal of the present rejection.

***Rejection Under 35 U.S.C § 112, First Paragraph, Written Description***

Claims 1, 5, 6 and 8-11 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor was in possession of the claimed invention at the time the application was filed. Applicant respectfully traverses.

Applicants have amended claims 1, 5 and 11 to correct the typographical error “heparan” to the correct term “heparin,” thus obviating the rejection.

Applicants respectfully request reconsideration and subsequent withdrawal of the present rejection.

***Rejection Under 35 U.S.C. § 102(b), Anticipation***

Claims 1, 2, 4, 6 and 10 stand rejected under 35 U.S.C. § 102(a) as anticipated by Greinacher *et al.*, “*Pregnancy Complicated by Heparin Associated Thrombocytopenia: Management by a Prospectively In Vitro Selected Heparinoid (ORG 10172)*” Thrombosis Research, volume 71; pages 123-126, (1993) (hereinafter Greinacher *et al.*”). The Examiner suggests that Greinacher *et al.* discloses the administration of Org 10172 (a combination of heparan sulfate, chondroitin sulfate and dermatan sulfate, or danaparoid) to a pregnant woman during antithrombotic therapy and that Greinacher *et al.* has already administered

glycosaminoglycans recited in the claims to a pregnant woman in need of antithrombotic therapy. The Examiner also suggested that the fact that the Greinacher *et al.* reference is silent regarding the inherent effect on labor and delivery does not negate anticipation with respect to the prevention aspect of the invention. Additionally, the Examiner also noted that the claims do not exclude women in need of antithrombotic therapy, nor are they limited to women having said problem with labor and delivery because they expressly recite prophylaxis

Applicants respectfully traverse. Applicants have amended the claims, without prejudice or disclaimer, to remove the term “prophylactically” and limited the claims to treating women with protracted term labor. These amendments further distinguish away from Greinacher *et al.*, and obviate this rejection.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

***Rejection Under 35 U.S.C. § 103(a), Obviousness***

Claims 1-4 and 8-10 stand rejected under 35 U.S.C. § 103(a) as unpatentable over over Laster, EP 1016410 (hereinafter “Laster”) in view of Einarsson, U.S. Patent No. 5,714,477 - claim 9 or Atad, U.S. Patent No. 4,976,692 - claim 8.

The Examiner suggests that Laster teaches the administration of glycosaminoglycans, preferably LMW heparin, heparan or dermatan, for the treatment of preeclampsia, and that although Laster does not exemplify the treatment of women, it would have been obvious to one having ordinary skill in the art at the time the invention was made to administer these products to treat pre-eclampsia with a reasonable expectation of success because it is suggested in the art.

having ordinary skill in the art at the time the invention was made to administer these products to treat pre-eclampsia with a reasonable expectation of success because it is suggested in the art.

The Applicants respectfully traverse. Reconsideration and withdrawal of the present rejection is respectfully requested based on the following considerations.

A proper obviousness inquiry requires consideration of three factors: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) whether or not the prior art would have taught, motivated, or suggested to those of ordinary skill in the art that they should make the claimed invention (or practice the invention in case of a claimed method or process); and (3) whether the prior art establishes that in making the claimed invention (or practicing the invention in case of a claimed method or process), there would have been a reasonable expectation of success. *See* M.P.E.P. § 2143.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), has provided the controlling framework for an obviousness analysis. A proper analysis under § 103(a) requires consideration of the four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467.

The teaching, suggestion, motivation test is a valid test for obviousness, but one which cannot be too rigidly applied. *See KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1395 (U.S. 2007). While the courts have adopted a more flexible teaching/suggestion/motivation (TSM) test in connection with the obviousness standard based on the *KSR v. Teleflex* case which involved a mechanical device in a relatively predictable technological area, it remains true that,

*Pty., Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007) (since TSM test can provide helpful insight if it is not applied as rigid and mandatory formula, and since, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led chemist to modify known compound, in particular manner, in order to establish *prima facie* obviousness of new compound).

As described above, Applicants have amended the claims, without prejudice or disclaimer, to remove the term “prophylactically” and limited the claims to treating women with protracted term labor. Based upon the above, term labor (labor from the 37<sup>th</sup> week on) is quite different physiologically as well as pathologically from preterm labor and preterm conditions such as preeclampsia (a rapidly progressive condition characterized by high blood pressure and the presence of protein in the urine, which occurs after 20 weeks gestation, though it can occur earlier). The present invention involves administration to pregnant women at the 37<sup>th</sup> week or later of the gestational term with protracted term labor. A skilled artisan (doctor) would clearly distinguish the teachings within Laster (preterm labor conditions which involve pathological events during the 20<sup>th</sup> week of pregnancy) and would not be motivated to modify Laster to the present invention.

By amending the claims, Applicants have overcome the rejections based upon Laster, as well as overcoming the combinations of Laster with the above cited references. Applicants respectfully request reconsideration and withdrawal of the present rejection.

In view of the above amendments, Applicants believe the pending application is in condition for allowance.

**CONCLUSION**

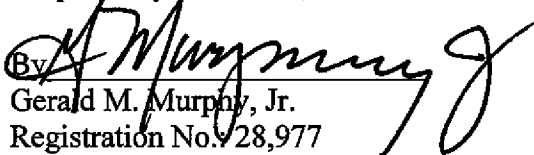
In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By 

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Enclosures: Exhibit 1 - The Preterm Parturition Syndrome

Exhibit 2- The Length of Uncomplicated Human Gestation